

ATTACHMENT 3

NAPROXEN SODIUM Soft Gelatin Capsules

Active ingredient (in each softgel)

Naproxen Sodium 220 mg (Naproxen 200 mg)

Purpose

Pain reliever/Fever Reducer

Uses

- Temporarily relieves minor aches and pains due to:
 - common cold
 - headache
 - toothache
 - muscular aches
 - backache
 - menstrual cramps
 - minor pain of arthritis
- Temporarily reduces fever

Warnings

Allergy alert: Naproxen sodium may cause a severe allergic reaction which may include: ■ hives
■ facial swelling ■ asthma (wheezing) ■ shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers. Naproxen sodium may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Ask a doctor before use if you have had serious side effects from any pain reliever/fever reducer.

Ask a doctor or pharmacist before use if you are:

- taking any other product that contains naproxen sodium or any other pain reliever/fever reducer
- taking other drugs on a regular basis
- under a doctor's care for any continuing condition

Stop use and ask a doctor if:

- any allergic reaction occurs. Seek medical help right away
- any new or unexpected symptoms occur
- symptoms continue or worsen
- you have difficulty swallowing or it feels like the softgel is stuck in your throat
- you develop heartburn
- stomach pain occurs with use of this product or if even mild symptoms persist
- pain worsens or lasts for more than 10 days
- fever lasts for more than 3 days
- painful area is red or swollen

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.



Directions

- Do not take more than directed
- Drink a full glass of water with each dose
- Age 65 and older: 1 softgel every 12 hours. Do not exceed 1 softgel in 12 hours, unless directed by a doctor.
- 12 –65 years of age: 1 softgel every 8 to 12 hours. For the first dose you may take 2 softgels within the first hour. Do not take more than 2 softgels in a 8 to 12 hour, or 3 softgels in a 24 hour period.
- Under 12 years of age: Ask a doctor.

Other information

- **Each softgel contains:** sodium 20 mg
- Store between 20-25°C (68-77°F)
- Avoid high humidity and excessive heat [40°C (104°F)]
- See side panel for lot number and expiration date.
- Do not use if carton or blister unit is open or torn.

Inactive ingredients

To be determined

Questions or comments?

To be determined

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To be determined